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Development and Pilot Testing of 24/7 In-Ambulance Telemedicine for Acute Stroke: Prehospital Stroke Study at the Universitair Ziekenhuis Brussel-Project

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Key Words

Telemedicine · Prehospital · Emergency care · Stroke · Diagnostic techniques and procedures

Abstract

Background: In-ambulance telemedicine is a recently developed and a promising approach to improve emergency care. We implemented the first ever 24/7 in-ambulance telemedicine service for acute stroke. We report on our experiences with the development and pilot testing of the Prehospital Stroke Study at the Universitair Ziekenhuis Brussel (PreSSUB) to facilitate a wider spread of the knowledge regarding this technique. **Methods:** Successful execution of the project involved the development and validation of a novel stroke scale, design and creation of specific hardware and software solutions, execution of field tests for mobile internet connec-

tivity, design of new care processes and information flows, recurrent training of all professional caregivers involved in acute stroke management, extensive testing on healthy volunteers, organisation of a 24/7 teleconsultation service by trained stroke experts and 24/7 technical support, and resolution of several legal issues. **Results:** In all, it took 41 months of research and development to confirm the safety, technical feasibility, reliability, and user acceptance of the PreSSUB approach. Stroke-specific key information can be collected safely and reliably before and during ambulance transportation and can adequately be communicated with the in-hospital team awaiting the patient. **Conclusion:** This paper portrays the key steps required and the lessons learned for successful implementation of a 24/7 expert telemedicine service supporting patients with acute stroke during ambulance transportation to the hospital.

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Introduction

Over the previous decades, much progress has been achieved on in-hospital stroke management, but a scalable solution to optimize prehospital care has not yet been established. Solving this problem would speed up treatment initiation by early activation of the in-hospital stroke response, curtail the risk of misdiagnosis, reduce the proportion of missed opportunities for treatment with intravenous thrombolysis [1] and/or endovascular treatment [2], and avoid patient admission to inadequate clinical facilities [3]. Expert prehospital care may also help avoid secondary brain damage by supporting the ambulance personnel to rapidly obtain and maintain homeostasis during ambulance transportation. The teleconsultant can assist the ambulance personnel to correctly manage airway protection, blood oxygen saturation, arterial blood pressure, heart rate, cardiac arrhythmia, decreased level of consciousness, dysglycemia, and administration of supportive measures (e.g. anti-emetics, analgesics). Furthermore, a considerate level of knowledge and expertise are required to efficiently engage in the complex patient-doctor interactions that are common in acute stroke, and to make appropriate medical decisions under time pressure. For these reasons, stroke diagnosis and patient selection by paramedics may not be the optimal approach [4].

The 'Mobile Stroke Unit' is an alternative way to improve prehospital stroke management [5–7]. This is an exceptional technical achievement, but the price tag of integrating computed tomography scanners into sizable emergency vehicles and the staffing costs for the accompanying highly trained personnel are likely to limit the widespread application of this strategy to densely populated regions with well-developed traffic infrastructure and favourable budgetary prospects [8]. Recent cost-effectiveness analyses situate mobile stroke units at the limit of societal acceptability, depending on willingness-to-pay thresholds and on the population density [9, 10]. These costs may be reduced by using telemedicine, which is an alternative solution to bridge the gap to prehospital stroke care by bringing medical experts virtually to the patient's location. Research on prehospital telemedicine for stroke (telestroke) is recommended by professional associations [11], but available solutions and evidence are scarce. This is mainly due to the recent coming of age of crucial components, the most important among them being the broadband mobile internet. Previous mobile telecommunications (3G or less) were deemed inadequate for reliable audio-video communication in moving am-

bulances [12]. Attributable to low available bandwidth, the TeleBAT project was limited to the transfer of a 320×240 -pixel image every 2 s [13, 14]. The Aachen project was the first to perform real-time prehospital telemedicine in stroke patients, leveraging the use of parallelized data channels. However, the study population was limited and the service was offered only during office hours, resulting in no conclusive advantage of prehospital telemedicine over best emergency care [15]. The need for a reliable solution motivated us to establish a scalable and workable system for 24/7 telemedicine support for acute stroke patients.

This paper aims at describing in detail the best practices and our experiences with the development and implementation of the Prehospital Stroke Study at the Universitair Ziekenhuis Brussel (PreSSUB) to facilitate widespread use of in-ambulance telestroke. Additionally, we report on the results of the PreSSUB-I pilot study.

Methods

Most of the following steps were performed chronologically; yet some processes overlap and were partially performed in parallel with other actions.

Conceptualization

In September 2010, we started mapping all relevant elements of the acute stroke care process based on extensive interviews with professional caregivers (stroke experts, emergency physicians, radiologists, emergency nurses and ambulance personnel). Next, various methods for speeding up this process were explored by integrating prehospital telemedicine with standard in-hospital care. Several commercially available systems were looked into and discarded for being inadequate to allow prehospital telestroke. Therefore, we decided to develop a system based on our design specifications for hardware, software and work processes. Among others, these specifications included (1) safety of all present in the ambulance during emergency transportation, (2) guaranteed data security to assure patient privacy, (3) compliance with all legal and regulatory aspects of emergency care, (4) scalability of the system to any type of ambulance at low cost and based on the 'plug-and-play' principle to facilitate widespread implementation, (5) no interference with the regular workflow or standing operating procedures of the ambulance personnel, (6) live transfer of key vital parameters, (7) robustness and reliability of the technology, (8) capability for the teleconsultant to observe the patient from head-to-toe with adequate resolution for evaluation of the patient's eyes and facial expressions while fixated on a stretcher in a moving ambulance, (9) user-friendliness and rapid system start-up, (10) integration with the in-hospital acute stroke care process through advanced notification of the in-hospital team and rapid report generation and communication, (11) live bidirectional audio and visual communication, with special attention for the functionality that allows the patient to see the teleconsultant while lying in a natural position, (12) acceptance by expert teleconsultants and

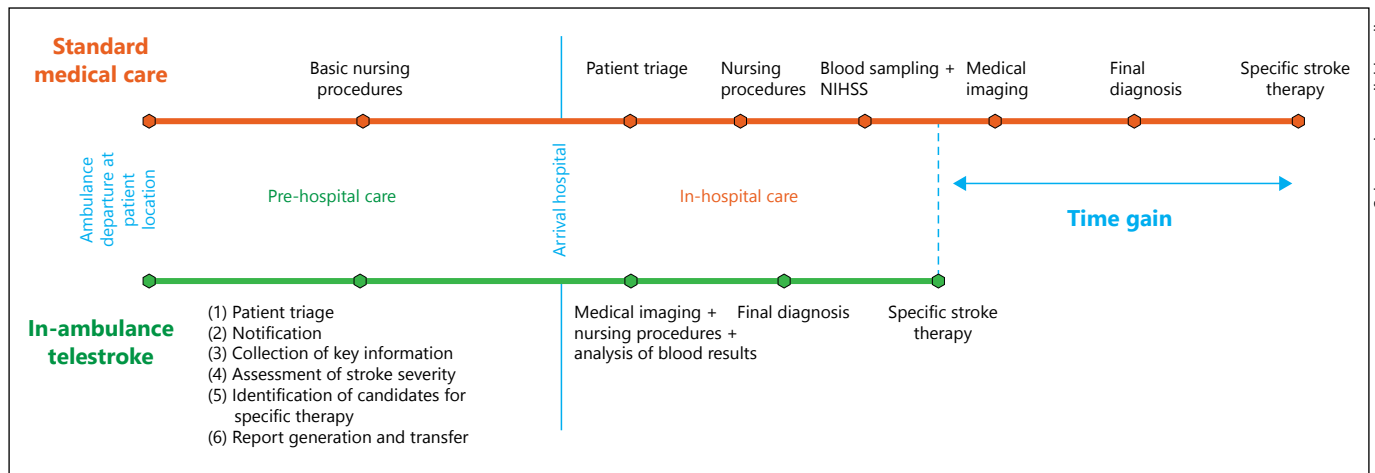


Fig. 1. Visualization of acute stroke care processes under standard medical care (upper line), and using in-ambulance telemedicine (bottom line). Rationale for potential time gain using in-ambulance telemedicine.

their employers based on seamless integration into their daily practice and respect for a healthy work-life balance (i.e. avoid being confined 24/7 to a stationary workstation but establish a mobile solution based on laptop computers and wireless connectivity). We, therefore, decided to design a novel clinical pathway leveraging digital communication for integration of all actors involved in acute stroke care. For every patient with suspicion of acute stroke, we bring a stroke expert virtually into the ambulance for (1) patient triage, (2) prehospital notification of the in-hospital team, (3) collection of key information (e.g. patient identity and demographics, vital parameters, clinical presentation, medical history, premorbid functional state, concomitant medication), (4) assessment of stroke severity, (5) identification of candidates for specific stroke treatment (e.g. thrombolytics, endovascular approaches, aggressive blood pressure lowering, neurosurgical interventions), and (6) to automatically generate and send a report containing all this information to the in-hospital team (fig. 1). This approach allows speeding up of in-hospital processes for stroke diagnosis and treatment, with the potential to halve the delay from stroke onset to initiation of specific stroke therapy.

Development and Testing of an In-hospital Prototype

The first prototype was built in the summer of 2011. It was a stationary construction based on a Mobotix® camera and local area network connectivity. This set-up allowed bidirectional audio communication but only unidirectional video communication, with the ability to remotely zoom, pan and tilt the camera. The main goal of this prototype was to evaluate the usability of standard stroke scales in the prehospital telestroke setting. This test led the physicians to conclude that the Glasgow Coma Scale (GCS) can be assessed through telemedicine. The National Institute of Health Stroke Scale (NIHSS), however, is not suitable for telemedicine application in the prehospital setting as it fails to meet the standards for patient safety and autonomy (support by a trained caregiver at the patient's bedside is required). As a consequence, we focused on the development of a novel clinical scale for rapid assessment of stroke severity via telemedicine without assistance by a third party.

Development of the UTSS

The unassisted telestroke scale (UTSS) was developed between October 2011 and August 2012 and was subsequently integrated into a transportable bedside prototype for in-hospital telemedicine using tailor-made software. Stroke severity was assessed in 45 patients with suspicion of acute stroke by bedside examination using the NIHSS and by teleconsultation using the UTSS. We concluded that the UTSS is a rapid, reliable and valid tool for unassisted assessment of stroke severity through telemedicine [16].

Development of an In-Ambulance Prototype and Validation of the UTSS

We produced a second-generation prototype, dedicated to use in ambulances. In September and October 2012, we investigated the technical feasibility and the reliability of the UTSS in healthy volunteers mimicking 41 stroke syndromes during ambulance transportation. We concluded that remote assessment of stroke severity in fast-moving ambulances using a system dedicated to prehospital telemedicine, 4G technology, and the UTSS is feasible and reliable [17].

Hardware and Software Development

Next, we focused on improving the ergonomic aspects of hardware and software in preparation for use in a real-life emergency environment. Several collaborations with commercial partners were forged. Materialise NV (Leuven, Belgium) designed and delivered the 3D-printing of the casing and developed a tailor-made ambulance clicking and mounting system. By integrating several commercially available off-the-shelf components into the 3D-printed casing, we created the final prototype.

The software platform was developed in close collaboration with IXSYS (Hasselt, Belgium) and had the following functionalities: (1) web-based access and log-in, (2) multiple decision support tabs including the UTSS (fig. 2), (3) automatic report-generation, (4) notification of the in-hospital team via short messaging service, (5) automated life transfer of the patient's name, sex and age based on data from the electronic identity (eID) card, (6) au-

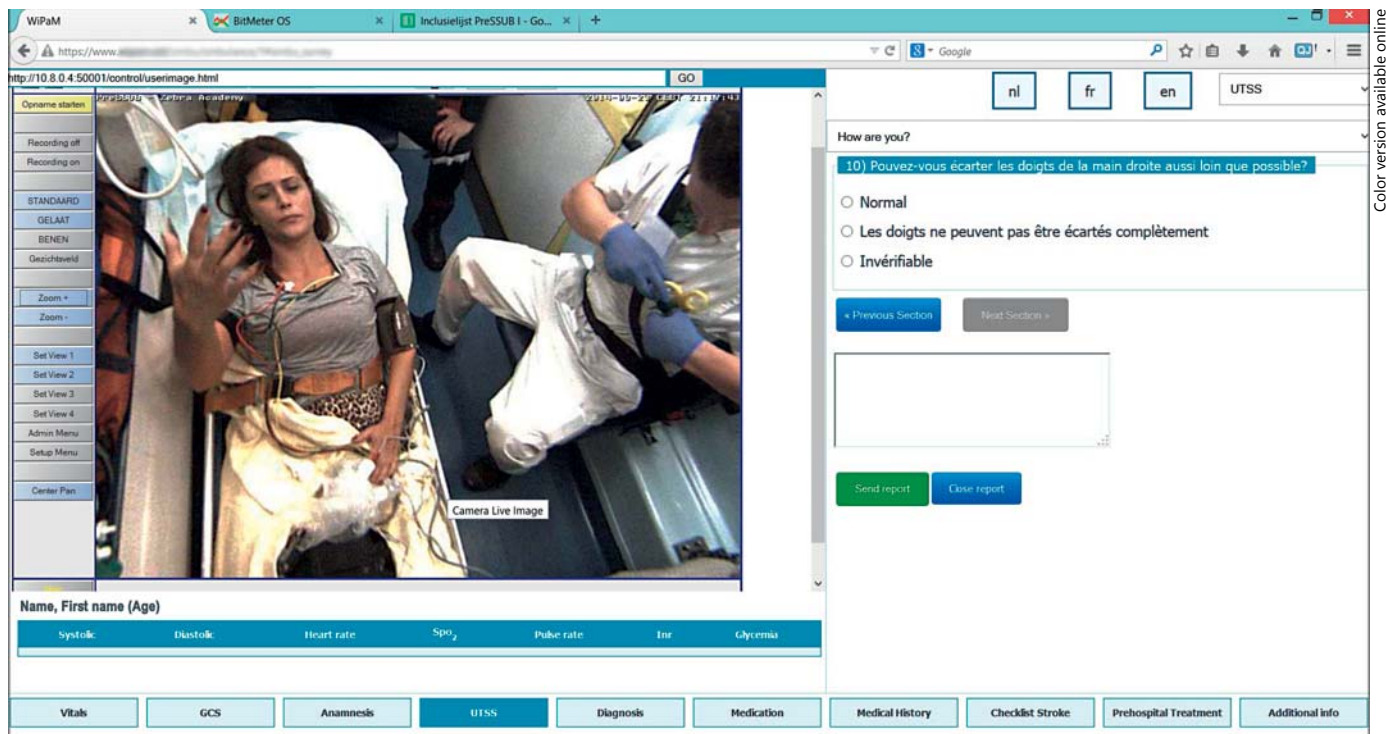


Fig. 2. Screen capture from the teleconsultant's laptop computer showing the telemedicine platform during consultation with the first patient in the PreSSUB-I study. The view illustrates the assessment of the UTSS (i.e. item 10-spreading the fingers of the right

hand) in the language preferred by the patient. Navigation between the submenus of the clinical decision support system is facilitated via touch screen activation of the buttons at the bottom.

tomated and live transfer of systolic and diastolic blood pressure, blood oxygen saturation, heart rate and glycemia, (7) access to the video stream of the Mobotix®-camera, and (8) availability in three languages: Dutch, French, English.

The software platform was secured using HyperText Transfer Protocol Secure encryption, access role control and end-to-end encryption. A Virtual Private Network connection and server were installed and managed by Futureweb (Herfelingen, Belgium) to forward the video stream from the Mobotix®-camera. A commercially available 4G router (RUT550 LTE, Teltonika, Vilnius, Lithuania) was installed in the ambulance and connected to 2 antennas on the ambulance roof. This router connected the PreSSUB system via WiFi to the 4G mobile network. A proprietary power box was developed and installed in the ambulance to power both the device and the router and to ensure 24/7 availability. Teleconsultants were provided with laptops and 4G modems to perform teleconsultations (fig. 3).

Final Tests on Healthy Volunteers

We performed several tryouts with healthy volunteers in various ambulance types to critically assess the scalability and feasibility of our approach. These tests established the compatibility of the system with at least 4 common ambulance types and corroborated the robustness and stability of the mobile Internet connection, the simple one button activation with short start-up times of the device, the overall safety, the consistency between the transferred and

received data, and the short time required to perform a prehospital teleconsultation. After 100 successful simulations, we were ready to use the technology in a real-life emergency setting.

Training and Information

In December 2013 and January 2014, all caregivers involved in acute stroke were informed in detail about the aim of the project and the functionalities of the PreSSUB system. Five stroke experts who volunteered to partake in the 24/7 teleconsultant service received training on the optimal use of the telemedicine platform. Instructions for the ambulance personnel involved contacting the teleconsultant via cellphone, activating the PreSSUB device in the ambulance, introduction of the patient's eID card in the device, and use of the medical devices for registration of vital parameters. All emergency physicians, neurologists and radiologists on call were informed on the access to the prehospital telemedicine report.

Certifications and Legal Issues

To guarantee the safety of patients and caregivers aboard the ambulance, we pursued certification of the system by a certified ambulance equipper (Autographe, Wavre, Belgium). The research protocols for all clinical trials and tests with healthy volunteers were approved by the ethics committee of the UZ Brussel. Informed consent based on 'opt-out sampling' is applicable for interventional in-ambulance telemedicine trials. All legally required



Color version available online

Fig. 3. The PreSSUB 3.0 system. The teleconsultant uses a lightweight laptop computer to access the telemedicine platform. Consultations can be performed from virtually any location, as

long as mobile broadband connectivity is available (a). The telemedicine device is securely mounted to the ceiling of the ambulance (b).

insurances were obtained through the legal department of the UZ Brussel, and the UZ Brussel has accepted liability for the implementation of in-ambulance telemedicine in the research setting.

Feasibility of Ambulance-Based Telemedicine Study

Starting in February 2014, 24/7 teleconsultation service was provided for all patients (>18 years) during emergency ambulance transportation irrespective of their prehospital diagnosis, using the system described earlier (see Hardware and software development). Forty-three patients were included in the trial, yielding encouraging results regarding safety, feasibility, reliability, and user-acceptance of in-ambulance telemedicine [18]. Improvement of mobile connectivity and more convenient communication of the vital parameters were selected as the main future directives. The first goal was accomplished by optimization of the router and by roll out of 4G coverage in the Brussels region during the summer of 2014. For the latter, the ambulance nurse requested the use of the standard monitoring equipment to communicate the vital parameters orally rather than use telemedicine-dedicated equipment for registration and automated communication of the parameters.

PreSSUB-I Trial

We evaluated the system specifically in patients with suspicion of acute stroke because telecommunication may be especially challenging in this situation due to confusion, decreased conscious-

ness, or language problems. We also tested the reliability and feasibility of novel in-hospital reporting and alarm systems. In September and October 2014, we performed a pilot study on in-ambulance telemedicine confirming the safety, feasibility, reliability, and user-acceptance of our concept in stroke patients (c.f. Results).

Technical Support

During the clinical trials, 24/7 technical assistance was organized by 1 full-time technician and 2 back-up technicians. Agreements were made with the relevant commercial partners to provide technical support within 24 h. A written protocol and standing operating procedures are in place to assure optimal technical performance. This involves, among others, a weekly technical check-up of the battery status, connectivity and robustness of the ambulance fixation system. A backup system is available.

Results

In the PreSSUB-I pilot study, a team of four senior stroke experts provided 24/7 on-call emergency availability for in-ambulance telestroke. Over a period of 6 weeks,

the ambulance with the telemedicine system installed performed 187 emergency interventions, of which 16 interventions involved patients with suspicion of acute stroke (8.6%). Activation of the telemedicine system was attempted in 16 eligible patients (activation rate 100%), yielding on average 2.7 telestroke interventions per week. The teleconsultants were able to log in timely on the platform in 100% of the cases. Ninety-four per cent of the teleconsultations was established successfully; one major technical issue occurred due to battery malfunction of the in-ambulance device. The median duration of the teleconsultation was 9 min (interquartile range (IQR) 8–13 min), during which the following information was collected: patient name (60%), age (66%) and sex (80%; communicated automatically via e-ID or orally); vital parameters including systolic blood pressure (93%), diastolic blood pressure (87%), heart rate (87%), blood oxygen saturation (87%), glycaemia (87%), temperature (13%), and cardiac rhythm (67%); anamnesis regarding the presenting symptoms and their evolution (100%); GCS (87%); assessment of the stroke severity using the UTSS (87%); concomitant medication (87%); medical history (93%); premorbid functional state based on the modified Rankin Scale (47%); proxy contact information (20%); teleconsultant's prehospital diagnosis (100%); checklist for possible treatment with intravenous thrombolysis (73%); and description of the prehospital therapy administered by the ambulance personnel (87%). Automated prehospital reports containing this medical data were generated in 100% of the teleconsultations and screen recordings from the teleconsultant's laptop were available for delayed reassessment in 93% of cases. The teleconsultants identified 12 patients (80%) with possible stroke or TIA, which was concordant with the inhospital diagnosis in 10 patients (83%). Two patients were diagnosed with stroke mimics due to partial epilepsy and hyponatremia. No stroke diagnosis was missed during in-ambulance telestroke consultation. The inhospital notification alarm at the UZ Brussel was activated in 7 patients presumed to be eligible for specific stroke treatment. The alarm was not activated in 2 patients considered to have another diagnosis and in 1 patient with a transportation duration that was too short to allow activation. Five patients were transferred to hospitals not equipped with the alarm system. The median maximal and average upload speeds (from the teleconsultant to the ambulance) were 196 kB/s (IQR 45–252) and 40 kB/s (IQR 20–145), respectively. The median maximal and average download speeds (from the ambulance to the teleconsultant) were 407 kB/s (IQR 263–1,195) and 127 kB/s (IQR 101–158), respectively.

The median total data transfer per consultation was 37 MB (IQR 24–122) for upload and 176 MB (IQR 60–193) for download.

Discussion

The first ever 24/7 in-ambulance telemedicine service for acute stroke patients was successfully implemented after ca. 3 years of preparation. The safety, feasibility, reliability, and user friendliness have been shown in pilot studies.

The creation of specific hardware and a dedicated software platform, the inception of a novel stroke scale, and the involvement of all stakeholders were the most challenging obstacles in our endeavour. Especially the latter was a decisive yet continuous effort that required extensive multidisciplinary collaboration with 112-call takers, the Fire department, the ambulance personnel, the departments of Emergency Care, Neurology, Radiology, Communication and Information Technology, the hospital management, and the (local) government.

Most procedures for the implementation of in-ambulance telemedicine described in this paper are applicable to other developed countries, underlining the potential to realize this technique on a large scale. Some variables may be region-specific and may require adaptation. For instance, mobile internet access may be limited in certain areas, and organizational, financial and legal aspects of stroke care may vary. The impressive progress in mobile satellite communication technologies is a valuable opportunity, as is the increasing awareness among decision takers responsible for healthcare. Furthermore, it is reasonable to expect that future initiatives on in-ambulance telemedicine will be less time consuming and less expensive as the technology and service will become commercially available.

We expect stroke patients to benefit from in-ambulance telemedicine, thanks to the prevention of secondary brain damage during the prehospital phase (teleconsultant supports the ambulance personnel to obtain and maintain homeostasis) and thanks to the boosting of in-hospital stroke treatment (immediate communication of decisive medical data will maximize the identification of candidates for specific stroke treatments and will reduce the delays to initiation of these treatments). In the future, patients may be offered more opportunities to participate in therapeutic clinical trials [8].

Not surprisingly, the recent publications on the efficacy [2] and cost-utility [19] of endovascular treatment

for acute ischemic stroke, result in a paradigm shift towards optimization of prehospital stroke diagnosis, identification of suitable candidates for recanalization therapy, and patient triage to appropriate centres. The virtual presence of a stroke expert may in time prove to be a unique advantage in this setting, especially if the medical decision making is reinforced by a validated triage algorithm. In-ambulance telemedicine may be leveraged to explore innovative prehospital therapeutics and diagnostics and, obviously, should not be limited to acute stroke management but may also be a catalyst to advance care in adjacent fields (e.g. cardiorespiratory emergencies, trauma and disaster medicine).

Conclusions

24/7 in-ambulance telemedicine support for acute stroke patients is feasible and stroke-specific information can be collected and communicated to the in-hospital team during ambulance transportation. This approach has the potential of a reliable and scalable solution to relevantly improve stroke care. We have experienced several barriers, among which are the development of dedicated hardware, software and medical solutions, and the commitment of various stakeholders.

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